EXHIBIT 2
Declaration of Richard H. Schwartz, M.D.
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HEPATITIS B VIRUS INFECTION FROM A NEEDLE STICK

To The Editors:

A new problem has recently occurred in our cities. Some people, usually children, have needle sticks from syringes used by intravenous drug users and discarded in a public place.[1–8] Hepatitis B virus (HBV), hepatitis C virus and HIV-1 are transmitted by parenteral exposure to contaminated blood[9]:

A 4-year-old boy was admitted in the hospital because of acute hepatitis B virus infection, with HBV surface antigen and IgM surface antibody tests positive. By history the only risk factor was an antecedent injury from a needle discarded by a neighbor known to be infected with HBV and HIV-1. His parents did not consider the incident important and he did not receive immunoprophylaxis. His mother and father are HBV surface antigen- and core antibody-negative. HIV-1 antibodies were not detected in the child. This boy became a chronic carrier of HBV surface antigen for more than 2 years without response to treatment with interferon.

Hepatitis B virus infection from occupational needle sticks has been documented in health care workers.[10, 11] The transmission risk is between 6 and 30%, depending on the absence or presence of HBV e antigen.[12] If the health care worker is completely vaccinated, there is probably no risk.[13]

HBV is very infectious, because of the high concentration in blood (10^9 to 10^{12}/ml)[10] the resistance of the virus to external conditions[10, 14] and the small inoculum needed for transmission.[1, 10]

Needles and syringes are discarded by intravenous drug users, who have an high prevalence of HBV infection. In Barcelona the rate of HBV carriers varies between 6.4 and 17%.[15] In several studies HBV surface antigen has been demonstrated in syringes discarded in the street and collected in Florence, Italy[3] and Barcelona, Spain,[2, 16] and HBV DNA in New Haven, CT,[17] and Barcelona.[3]

Our case confirms that the risk of HBV infection exists in the case of an accidental needle stick from a hypodermic needle and syringe discarded by an intravenous drug user in a public place. Postexposure immunoprophylaxis against HBV with vaccine and hyperimmune gamma-globulin in the management of such an accidental exposure should be considered if the child has not already had a complete hepatitis B vaccination.

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EVALUATION OF RAPID STREPTOCOCCAL DETECTION TESTS

To The Editors:

CLIA (Clinical Laboratory Improvement Act, 1988)-waived tests are by definition, "simple to operate and so accurate that

error is very unlikely."[1] They can be performed in the office without the requirement for a CLIA certification. In addition to waived tests for hemoglobin, dipstick urinalysis, blood glucose and urine pregnancy tests, there are at present three waived antigen detection tests for presumptive identification of group A streptococci from throat swabs. These are: OSOM™ Strep A Test (Wyntek Diagnostics, San Diego, CA), QuickVue™ In-Line Strep A Test (Quidel, San Diego, CA), and Binax Now™ (Binax Inc., Portland, ME). These individual tests cost between $3.50 and $4.50 to purchase and results are obtained in about 5 min.

We compared results of the OSOM™ test and the QuickVue™ test with that of concomitant sheep blood agar throat cultures after aerobic overnight incubation at 35°C. During a 3-week period ending May, 1997, 258 rayon-tipped throat swabs were analyzed for strep A antigen by a registered laboratory technologist while the patients and their parents waited in our office laboratory. For the 155 culture-negative specimens the specificity for both antigen detection tests was 100% (no false positives). For the 103 culture-positive specimens (40% of the total), the sensitivity was 95% and 87% for OSOM™ and QuickVue™ Strep A tests, respectively, almost identical with the respective package insert performance data.

Additional analysis of our data revealed that sensitivity was directly related to the number of colonies of group A strep. For 3+ and 4+ growth of group A strep colonies on the agar plate, both tests were 100% sensitive. For 1+ culture, OSOM™ Strep A test was 83% sensitive (5 of 6) whereas Quick Vue™ sensitivity was 33% (2 of 6). For 2+ culture, OSOM™ was 86% (24 of 28) sensitive whereas The QuickVue™ sensitivity was 72% (20 of 28). The negative predictive values for the OSOM™ and QuickVue™ Strep A tests were 97% and 92%, respectively.

The OSOM™ color immunochromatographic dipstick Strep A test performed at least as well as the best of the many rapid strep antigen detection tests that we evaluated in our office laboratory during the past 12 years. There are few reagent steps, the color endpoint is distinct, the 50 test strips are contained in a small easy-to-store cylinder and there is much less plastic for our biodisposable trash. Our nurses appreciated its simplicity and rapidity. The OSOM™ Strep A Test provides three levels of procedural controls with each test. Each kit contains additional standardized positive and negative controls which are to be tested twice per kit. According to the package inserts from all three waived tests mentioned above, for a negative result it is recommended that a routine throat culture be obtained.

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1. CLIA Q & A. Clinical Laboratory Management Association, Malvern, PA, and the American Association for Clinical Chemistry, Washington, DC, 1993.

CIRCUMCISION AND INFECTIOUS DISEASES

To The Editors:

In the provocatively entitled article, "Prophylactic neonatal surgery and infectious diseases,"[1] Weiss argues that male circumcision is good for the world. "Here we go again," as one of our leaders said in a past presidential campaign. This article, which is a rambling melange of facts, opinions and speculations, fails to provide the one standard for judgment: What is the risk:benefit ratio of the procedure? Weiss offers us no basis for assessing his clarion call to circumcise.

Lacking the necessary facts he drowns us in text, which ranges from preposterous to incomprehensible. Let me cite some examples of both. There are, he tells us, 1.8 billion cases of diarrhea, 400 million cases of malaria, 200 million cases of schistosomiasis and 4 million deaths caused by respiratory diseases. These numbers are within the accepted norm of current prevalence, as is the 1994, 25 million prevalence of HIV infection. Without a transition, however, he tells us that, "For millennia the male's preputial cavity has acted as a cesspool for infectious agents transmitting diseases. . . ."

He promises us that, "This paper is an attempt to relate how surgery. . . can prevent many of the world's infectious diseases when the prepuce is removed neonatally." Are we to infer that circumcision will prevent diarrheal disease, malaria, schistosomiasis (about which more later) and respiratory disease? There is some evidence of greater susceptibility to AIDS in Africa among the noncircumcised men, because other sexually transmitted infections may traumatize the foreskin, but there is no comparable evidence from elsewhere.

Further in his article he argues that schistosomiasis haematobium in Egypt has a higher prevalence in men and boys than in girls and women and from that he invokes a wholly speculative hypothesis that *Schistosoma haematobium* invades the body though the prepuce and that the preputial skin is "immunodeficient," therefore allowing an easy penetration of the cercariae. The sex difference in the prevalence of urinary schistosomiasis relates to exposure (boys and men have occupational contact with water) and the proposed deficiency of preputial skin to prevent infection is sheer fantasy.

In the similar vein he jumps to the conclusion that because HIV "... found free in human milk [is transmitted] by absorption of infected cells through the feeding infant's mucous membrane [.]." "Why not transmission in a similar fashion when HIV-infected cells contact the preputial mucous membrane?"

These are but a few examples of Weiss' preposterous speculations. In the category of incomprehensible writing belong the following excerpts. After arguing that penile hygiene is not properly supervised and that children often neglect it, he goes on, "Teenage, the time of increased and intense sexual awareness, results in exposure of penis to interest by the male and at times the female attendant." Later he adds, "The married and working male has another set of demands on this organ, but cleanliness remains an imperative."

He concludes with a plea for better quality circumcision, which I applaud, but argues that pain should be reduced by the expert's speed of the procedure. Yes, it is important not to linger, but pain is relieved by proper analgesia and current literature strongly supports it.

His conclusion is a reprise of his introduction: (1) infections are the primary source of morbidity and mortality today; (2) prophylactic surgery (i.e. circumcision) prevents infections. *Ergo*, let's do it!

Until such time as a properly conducted epidemiologic analysis of the effects of circumcision is carried out, when the full extent of its putative benefits and the documented risks is explored, routine circumcision remains a ritual and not a legitimate health measure.

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